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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,316	04/21/2004	Arthur A. Gertzman	X-9468	4219

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EXAMINER	
BERKO, RETFORD O	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,316	GERTZMAN ET AL.	
	Examiner	Art Unit	
	Retford Berko	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,7,8,10 and 21-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,7,8,10 and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement: The Preliminary Amendment filed April 21, 2004 is acknowledged.

Status of Claims

1. Claims 2, 7, 8, 10 and 21-25 are pending.

2. Claims 1, 3-6, 9 and 11-20 are cancelled by applicant's Preliminary Amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 2, 7, 8, 10 and 21-25 are rejected as unpatentable under 35 U.S.C. 103(a) over Boyce et al (US 6, 294, 187; filed February 23, 1999) in view of Breitbart et al (US 5, 700, 289) further in view of Sander et al (US 5, 356, 629).

Claims 21-25 are directed toward bone composition comprising osteoinductive bone particles in aqueous medium in the form of a hydrogel comprising chitosan and sodium alginate; the composition contains growth factor additives such as transforming growth factor and cellular materials (living cells, cell elements, fibroblasts, epithelial cells etc. The bone particles are added at 5-50% concentration (w/w); the molecular weight of the hydrogel ingredient is 10,000 to 300, 000; the endothelial cells are added to give 10^5 cells/ml and the pH of the suspension is near physiological pH.

Claims 2, 7,8 and 10 are directed toward the bone particle size (100-850 microns), the concentration of bone particles and the number of cells present in the carrier aqueous solution.

Boyce et al (Patent '187) disclose osteoimplant composition comprising bone particles in physiological saline (col 2, lin 45-50, col 3, lin 20 and col 11, lin 20-25) wherein the composition exhibits biological properties as in applicant's instant claims (e.g. osteoconductivity and/or osteoinductivity—col 7, lin 1-10). According to Boyce, the bone particles can optionally be sieved to produce particles of a specific size (col 4, lin 50-55 and continuing to col 5, lin 1-25) and further discloses bone particle content in terms of the wt% of the particles in the composition (col 5, lin 30-35, col 6, lin 15-25 and col 8, lin 50-55). Patent '187 also discloses the use of chitosan and hydrogels (col 8, lin 15 and col11, lin 1-10). Patent '187 also discloses the use of bioactive substances in the bone repair composition (e.g. transforming growth factor; col 9, lin 50-60).

Patent '187 does not teach the use of alginate and other souces of cells in the composition.

Breitbart et al (Patent '289) supplies the deficiencies of Patent '187 in that Breitbart et al disclose bone repair composition comprising cells such as stem cells, chondrocytes and mesenchyma cells (col 2, lin 45-60, col 4, lin 25-30 and col 14, lin 60). Additionally, Patent '289 discloses the use of both alginate and chitosan as the hydrogel forming ingredients (col 6, lin 35-40, col 10, lin 5-10, lin 40-45 and col 11, lin 35-40).

Sander et al (Patent '629) discloses a composition suitable for bone repair comprising biocompatible particles dispersed in a matrix than can be implanted into defective bone tissue (abstract, col 2, lin 35-40, col 3, lin 50-55 and col 5, lin 35-40). Patent '629 discloses the use of

drugs and other substances that can induce bone growth in the composition (col 4, lin 55-65; continuing to col 5, lin 1-15). More significantly, Patent '629 discloses that the biocompatible particles of any size may be used in the composition and that matrix material can be conveniently comminuted to the appropriate particle size of mixing (col 4, lin 30-39 and col 35-40).

One of ordinary skill in the art would be motivated to prepare a composition comprising bone particles and bioactive agents having osteoinductive properties such as growth factors to form a bone cement composition as disclosed in the prior art cited. By combining the methods disclosed in the prior art cited, one of ordinary skill would expect to obtain a composition that can be molded and implanted into a bone defective site in order to induce bone growth and repair while preventing or mitigating the possibility of infection at the injured site due to the antibiotic action of the drugs incorporated into the composition. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 7, 8, 10 and 21-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 14 of US Patent No. 6, 326, 018 and claims 1, 7, 22, 24, 28 and 29 of US Patent No. 6, 030, 635.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims in the instant application, similar to those of the patented claims, are drawn to a (a) a bone composition bone particles or powder in aqueous buffer at pH suitable for in-vivo application and having osteoinductive or bone repair as the biological property of the composition (b) the instant claims are drawn toward particle size, ingredients, and hydrogel forming components that are similar but identical to those in the patents issued to the same inventors.

3. The following prior art reference is cited for the record only as pertinent to applicant's claims but is not relied upon for the current rejection in the office action:

Wolfinbarger et al (US 5, 531, 791). The reference teaches cone composition in gel or hydrogel form comprising bone particles and optional components such as growth factors and osteoblats (abstract, col 4, lin 1-30, lin 50-60; col 5, lin 40-45, col 7, lin 20-25 and col 9, lin 20-35. The reference is not applied because it does not teach the use of alginate or chitosan in the composition.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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